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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Joseph D. Kuborn
Andrus, Sceales, Starke & Sawall, LLP
Suite 1100
100 East Wisconsin Avenue
Milwaukee, WI 53202-4178

EXAMINER	
PATEL, NATASHA	

ART UNIT	PAPER NUMBER
3766	

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05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,494	XUE ET AL.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amendment filed March 22, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed March 22, 2007 has been received and considered. By this amendment, no Claims have been amended, added, cancelled, or withdrawn. Thus, Claims 1-20 are still pending in the application.

Response to Arguments

1. Applicant's arguments filed March 22, 2007 have been fully considered but they are not persuasive.

2. Regarding the Fishler reference, Examiner considers that although the beats are selected, they are still representative of the electrocardiogram signal because they are a part of the signal. Furthermore, Fishler uses the one morphology feature to determine a total quantity of values because the morphology measurement data is taken at frequent intervals (see col. 2, lines 30-32). The measurement data stored in memory makes up the total quantity of values. Also, these values represent the beats because they were derived from the beats. Therefore, the total quantity of values represents the total quantity of beats, which represent the ECG signal. Finally, since the changes in the total quantity of values are used to indicate the progression or regression of CHF (see col. 2, lines 14-21), the data is in fact being used to assess repolarization abnormality since CHF patients would have abnormal cardiac repolarization.

3. Regarding the Schroeppel reference, the Examiner considers that the stimulator receiving heart-beat signals from the heart is an act of deriving a total quantity of representative beats because to derive is to receive and the heart-beat signals inherently have a quantity of representative beats within them (see col. 4, lines 10-12).

Furthermore, the computed time intervals make up the total quantity of values representing the total quantity of representative beats (see col. 4, lines 11-16).

4. Finally, regarding the Reinhold reference, the Examiner considers that the isolation of individual heartbeats from the EKG signal (see col. 7, lines 30-34) makes up the total quantity of representative beats. Furthermore, the act of using morphology to derive a specific value for the number of beats of each shape (see col. 9, lines 55-66) is evidence that a total quantity of values is being derived to represent the total quantity of beats. In other words, if there were 8 beats with Shape A, 6 beats with Shape B, and 3 beats with Shape C, then the total quantity of beats would be 17 beats. The total quantity of values would be 8, 6, and 3. The values are derived from the total number of beats. Finally, the values give insight into which shape predominates and therefore, suggests whether arrhythmia exists. Once again, an arrhythmia would suggest a cardiac repolarization abnormality.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Fishler et al. (US Patent 7,069,069).

7. Regarding Claim 1, Fishler discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal (see Abstract), the method comprising: deriving a total quantity of representative beats of the at least one electrocardiogram signal; using at least one morphology shape descriptor to determine a total quantity of values (see morphology measurement data) representing the total quantity of representative beats (see col. 2, lines 21-25), wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total quantity; a maximum morphology feature; minimum morphology feature; area morphology feature; amplitude morphology feature; slope morphology feature; time interval morphology feature (see col. 2, lines 39-46); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 2. lines 14-18). The examiner considers that the beats that are derived from the ECG signal are representative beats because they are selected (see col. 2, line 24). Finally, the examiner considers that an indication of heart failure will necessarily indicate an abnormality in cardiac repolarization.

8. Regarding Claim 2, Fishler discloses that the total quantity of representative beats comprises at least one beat representative of each lead of the at least one electrocardiogram signal (see col. 5, lines 20-34). The examiner considers since the two leads record two separate electrocardiograms and both electrocardiograms are utilized, then representative beats from both leads are present in the sample.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schroeppel et al. (US Patent 6,571,122).

11. Regarding Claim 1, Schroeppel discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal (see Abstract), the method comprising: deriving a total quantity of representative beats of the at least one electrocardiogram signal (see col. 3, lines 25-27); using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats (see col. 4, lines 11-21), wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total quantity; a maximum morphology feature; minimum morphology feature; area morphology feature; amplitude morphology feature; slope morphology feature; time interval morphology feature (see time intervals occurring between successive heart beats; col. 4, lines 12-16); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 4, lines 21-24). The examiner considers an abnormal heart variability is the result of an abnormal cardiac repolarization.

12. Claims 1, 3, 6,15, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinhold et al. (US Patent 4,531,527).

13. Regarding Claims 1 and 20, Reinhold discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal (see col. 5, lines 19-21), the method comprising: deriving a total quantity of representative beats (see col. 7, lines 28-34) of the at least one electrocardiogram signal (see col. 4, lines 30-40); and using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats (see col. 9, line 55- col. 10, line 10); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 10, lines 23-28). The examiner considers that an arrhythmia is a cardiac repolarization abnormality.

14. Regarding Claim 3, Reinhold discloses a template (see col. 9, line 66-col. 10, line 13 and col. 20, lines 14-16). Reinhold further discloses generating a template using at least one value (data) corresponding to at least one of the representative beats (see col. 10, lines 6-10). The examiner considers that the beat that is sufficiently different from all the templates is one of the representative beats to which the template is being compared (see col. 10, lines 3-6). Finally, the examiner considers that the comparison is used to determine a cardiac repolarization because the template classifies the ECG signals and the classification includes an 'alarm' criteria in the case of an abnormal cardiac repolarization (see col. 10, lines 45-47).

15. Regarding Claim 6, Reinhold discloses altering the template based at least in part on the at least one value corresponding to the at least one other of the representative beats (see col. 10, lines 6-10). The examiner considers that if the monitor

comes across a new 'sufficiently different beat,' then the template will be changed once again.

16. Regarding Claim 15, Reinhold discloses displaying data corresponding to at least one electrocardiogram signal (col. 11, lines 44-46). ST segments correspond to the ECG and office unit displays this data.

17. Regarding Claim 16, see rejection of similarly worded Claims 1 and 3 above.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 2 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) in view of Steinhaus et al. (US Patent 5,215,098).

20. Regarding Claims 2 and 17, Reinhold discloses leads carrying electrocardiogram signals (see col. 14, lines 37-47 and Figure 3). Reinhold does not disclose that a beat from each lead makes up the total quantity of representative beats. Steinhaus discloses a similar detection system (see col. 18, lines 56-53) that the total quantity of representative beats comprises at least one beat representative of each lead (10) of the at least one electrocardiogram signal (see col. 5, lines 35-40 and Figure 1). The examiner considers that since all the leads are represented by line 10 and line 10 goes

directly from the heart to the correlator 5, then the beats collected by each lead are all going into the correlator. It would have been obvious to one of ordinary skill in the art at the time of the invention to create a sample using beats from each of the leads as taught by Steinhaus in order to reduce the influence of errors that may be caused by something other than the heart, for example a lead dysfunction.

21. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) in view of Cohen et al. (US Patent 4,802,491).

22. Regarding Claim 4, Reinhold discloses comparing the ECG samples to the template (see col. 10, lines 3-6). Reinhold does not disclose a threshold. Cohen discloses that a similar cardiac monitor in which cardiac repolarization abnormality exists if a variation between the template and the at least one value corresponding to at least one other of the representative beats is greater than a threshold value (see col. 9, lines 48-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to use thresholds with the template comparison in order to catch more subtle changes (see col. 9, lines 43-45) as taught by Cohen.

23. Regarding Claim 5, Cohen discloses adjusting the alternation energy based at least in part on a level of noise in the at least one electrocardiogram signal (see col. 7, lines 10-23). Cohen does not disclose adjusting the threshold value due to the level of noise. However, it is well known and common in signal processing to adjust values to accommodate for noise. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the threshold value based on the level of noise, especially since the other values, which are being compared to the threshold value,

have been adjusted under the same circumstances. Being consistent in this manner, allows for a more accurate comparison between the ECG signal values and the threshold.

24. Regarding Claim 7, Reinhold does not elaborate on the signal processing techniques. Cohen discloses a similar monitoring device, which normalizes at least some of the values of the total quantity of values (see col. 2, lines 17-21). It would have been obvious to one of ordinary skill in the art at the time of the invention to normalize the values gathered in Reinhold's invention because it is a well known and common signal processing technique.

25. Regarding Claim 11, Cohen discloses tagging at least one value of the total quantity of values with a marker (see col. 2, lines 50-54). Once again, it is common to tag specific values in a string of values as a means of organizing the data and quickly finding values of importance at a later time.

26. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) in view of Cohen et al. (US Patent 4,802,491) and further in view of Thiagarajan et al. (US Patent 6,983,183).

27. Regarding Claim 12, Cohen discloses a marker (see col. 3, lines 40-44), but he does not disclose that the marker is a measurement that does not change over time. Thiagarajan discloses a marker that does not change over time (see col. 6, lines 8-13). The position and magnitude of the R-wave is a measurement that will not change considerably over time. Thus, it would have been obvious to one of ordinary skill in the

art at the time of the invention to use such a marker to detect abnormalities in the ECG signals to be evaluated for cardiac repolarization.

28. Regarding Claim 13, Cohen discloses that the marker is a measurement that changes over time (see col. 3, lines 40-44). The examiner considers that the different values are indicative of changing measurements and 'one particular time in its evolution' refers to a constant time interval at which these measurements are taken.

29. Regarding Claim 14, Cohen discloses using the marker as part of a discriminator of cardiac repolarization abnormality (see col. 3, lines 26-29). The marker-based analysis procedure described helps to detect and quantify alternation in waveform morphology. The examiner believes since alternation indicates repolarization abnormalities, the marker-based analysis is essentially indicating repolarization abnormalities.

30. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) in view of Arnold et al. (US Patent 5,713,367).

31. Regarding Claims 8 and 18, Reinhold discloses the selection and analysis of appropriate data segments (see col. 7, lines 35-50 and col. 11, lines 42-47). However, Reinhold does not elaborate on the selection process. Arnold discloses a first electrocardiogram signal representative of a first duration of time and a second electrocardiogram signal representative of a second duration of time, and wherein the first duration of time and the second duration of time are non-continuous (see col. 5, lines 42-52). The examiner considers that the characterization of only portions of the recorded ECG data means that there will be a portion of the signal representing one

duration of time and another portion of the signal representing another duration of time. The examiner considers that a portion of a signal is still a signal. It would have been obvious to one of ordinary skill in the art at the time of the invention to select various segments of the ECG signals for analysis since choosing two contiguous segments may inadvertently increase the chances of not noticing an abnormality.

32. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) and Arnold et al. (US Patent 5,713,367) as applied to Claims 8 and 18 above in view of DePasquale et al. (US Patent 6,847,840).

33. Regarding Claims 9 and 19, Arnold discloses administering a pharmacological agent that stresses the heart of the patient (see col. 3, lines 52-56) and obtaining an ECG signal (see col. 10, lines 10-23). Arnold does not disclose determining variations between ECG signals before and after administering the drug. DePasquale discloses introducing pharmacological intervention; obtaining the at least one electrocardiogram signal from the patient, the at least one electrocardiogram signal comprising a first electrocardiogram signal comprising beats prior to the administration of the pharmaceutical drug (see pre-dose curve) and a second electrocardiogram signal comprising beats after the administration of the pharmaceutical drug (see post-dose curve); and determining a variation between values of the total quantity of values that correspond to the first electrocardiogram signal and values of the total quantity of values that correspond to the second electrocardiogram signal (see col. 2, lines 25-36). One of ordinary skill in the art at the time of the invention would have found it obvious to compare the values from the first and second ECG signals to understand which

variations were attributed to the drug and which variations may be attributed to a problem in the heart, thereby improving signal processing and improve the accuracy of measuring alternans which in turn help detect abnormal cardiac repolarization (see '367, Abstract: 2nd sentence).

34. Regarding Claim 10, Arnold discloses a statistical analysis (see col. 8, lines 58-65). Arnold does not disclose the statistical analysis of the variation between pre-dose and post-dose ECG signals. DePasquale discloses statistically analyzing this variation (see col. 2, lines 43-48). Thus, it would be obvious to one of ordinary skill in the art at the time of the invention to perform a statistical analysis of any measurement acquired from an ECG signal in order to understand which variations are significant and which ones are attributed to noise and other sources of error.

Conclusion

35. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

36. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carl H. Layno
Acting Supervisory Patent Examiner
5/24/07

CARL LAYNO
PRIMARY EXAMINER

Natasha N Patel
Patent Examiner
Art Unit 3766